REMARKS

Favorable reconsideration of applicants' pending claims is respectfully requested in view of the above amendments and following remarks. Following the amendments, claims 2-5, 10, 17, 19, 20 and 22-27 are pending in the application, with claims 19 and 20 being in independent format.

Claims 16 and 21 have been cancelled. Independent claim 19 has been amended to clarify that the catheter device comprises a housing provided with at least one sealing site, with at least a portion of a rotating torque tube being positioned in the housing and a stationary liner extending from the sealing site in the housing. Claim 19 has further been amended to state that a liquid flood space is located between the liner and the torque tube, the flood space being provided with liquid by an infusion port provided in the housing. Support for these amendments can be found, for example in paragraphs [0030], [0032] and [0035] of the published specification. Independent claim 20 has been amended to clarify that the liner is spaced apart from the torque tube and that a flood space is located between the liner and the torque tube. Support for these amendments can be found, for example, in paragraph [0032] of the published specification. Claims 26 and 27 have been amended to conform to the language of amended claims 19 and 20.

It is urged that support for all the above amendments can be found throughout the specification and drawings as originally filed, and that none of the amendments constitute new matter. Applicants specifically reserve the right to pursue claims to any subject matter cancelled from the claims by the above amendments in one or more related applications.

Claim rejections under 35 USC §112, second paragraph

Claim 19 and the claims dependent from claim 19 stand rejected under 35 USC §112, second paragraph, as being indefinite. Specifically, the Examiner has objected to the term "infusion port supplying liquid to the liquid seal assembly". Following the above amendments, this phrase no longer appears in claim 19.

It is submitted that one of skill in the art, on being provided with the instant specification, would be able to fully determine the metes and bounds of all the pending claims, and that this rejection under 35 USC §112, second paragraph, can be properly withdrawn.

Claim rejections under 35 USC §102

Claims 2-5, 10, 16, 17, 19-21, 24 and 26 stand rejected under 35 USC §102(b) as being anticipated by US Patent 5,490,859 to Mische et al. This rejection is respectfully traversed.

As noted above, claims 16 and 19 have been cancelled from the application, thereby rendering the rejection of these claims moot.

The present application discloses and claims an aspirating catheter device having a liquid seal assembly that provides an air-tight, substantially friction-free seal around a rotatable torque tube (e.g., a high speed rotational driveshaft) operating in proximity to an area of high vacuum. Providing a reliable, air-tight, low friction liquid seal around a high speed rotational driveshaft is particularly challenging when the driveshaft lacks a continuous, "solid" surface and is provided, for example, as a coiled structure having gaps between turns of the coiled structure. Conventional sealing mechanisms, such as O-rings, bushings and bearings, which are typically used to provide a liquid seal for drive shafts of interventional catheters, are prone to leakage and frictional heating as the drive shaft rotates during operation of the devices. The pending claims are directed to devices that use a liquid-filled liner as a sealing assembly at sealing sites, thereby eliminating the need to use conventional sealing mechanisms and providing an air-tight, substantially friction-free seal around the rotating torque tube.

More specifically, amended independent claim 19 is drawn to an aspirating catheter device comprising, in part, a housing providing at least one sealing site, a rotatable torque tube operably connected to a drive system, a stationary liner surrounding the torque tube and extending from a sealing site in the housing longitudinally less than the axial length of the torque tube and terminating distally at an intersect area, and a liquid flood space located between the liner and the torque tube. Similarly, amended independent claim 20 is drawn to a medical device comprising, in part, a rotatable torque tube operably connected to a drive system, and a sealing

assembly, wherein the sealing assembly includes a liner surrounding and spaced apart from the torque tube and a flood space located between the liner and the torque tube.

The Examiner asserts that the device of Mische et al. "includes a torque tube (94) rotated by a drive system (24) and a liner (100) surrounding the torque tube". Applicants respectfully disagree with the Examiner's characterization of element 100 of Mische et al. as a liner.

Mische et al. describe an intravascular material removal device including an expandable material removal element 16 positioned at the distal end of a catheter assembly 14 and a drive assembly 12 connected to the catheter assembly 14 by a manifold assembly 22 (col. 4, line 66 – col. 5, line 6 and Fig. 1). Manifold assembly 22 includes a port 82 that communicates with a catheter sheath 90 connected to the distal end of manifold assembly 22 and that can be used to deliver fluids for infusion or negative pressures for aspiration (col. 10, lines 30-40, Fig. 1). At col. 11, lines 24-39, Mische et al. state "To further improve trackability, as well as to reduce friction between the outer surface of the drive shaft and the inner surface of the catheter sheath 90, a lubricious or low friction coating 100, comprised of a fluoropolymer and the like, is applied to the outer surface of the drive shaft 92. The coating 100 may be provided in the form of a sheath of a fluoropolymer which shrinks upon application of heat." It is submitted that coating 100 of Mische et al. is not equivalent to, and could not perform the same function as, the liner as recited in the current claims. Applicants have been unable to find any suggestion or teaching in Mische et al. of a stationary liner surrounding a rotatable torque tube as recited in claim 19, or of a liner that is spaced apart from a rotatable torque tube as recited in claim 20. Furthermore, Mische et al. do not teach or suggest a flood space located between a liner and a rotatable torque tube as recited in both claims 19 and 20. It is thus submitted that Mische et al. do not teach or suggest every element of independent claims 19 and 20.

Applicants note that claims 2-5, 10, 17, 24 and 26 depend from, and therefore encompass all the limitations of, independent claims 19 and 20.

It is urged that Mische et al. do not teach or suggest the presently claimed subject matter and that the rejection of claims 2-5, 10, 17, 19, 20, 24 and 26 under 35 USC §102(b) can thus be properly withdrawn.

Claim rejections under 35 USC §103

Claims 22 and 23 stand rejected under 35 USC §103(a) as being unpatentable over Mische et al. This rejection is respectfully traversed.

The Examiner asserts that it would have been obvious "to form the liner to have an inner diameter of about 0.03-0.04 inch" and "to form the liner to have a length similar to the length of the catheter, which is greater than about 6 inches" in view of the teachings of Mische et al. However, as discussed above, Mische et al. do not teach or suggest the subject matter of independent claims 19 and 20, from which claims 22 and 23 depend.

It is submitted that the teachings of Mische et al. would not have rendered the subject matter of claims 22 and 23 obvious to one of skill in the art at the time the invention was made, and that this rejection of claims 22 and 23 can therefore be properly withdrawn.

Claim 25 stands rejected under 35 USC §103(a) as being unpatentable over Mische et al. in view of US Patent 6,258,052 to Milo.

The teachings of Mische et al. are discussed above. Milo discloses a guidewire for crossing vascular occlusions comprising a guidewire shaft, a drive member rotatably disposed within and along a longitudinal axis of the guidewire shaft, an actuator connected to a proximal end of the drive member, and an asymmetrical rotating tip attached to a distal end of the drive member. The reference teaches that the guidewire shaft may include a coiled wire and a polymeric tube formed, for example, from polyimide or heat shrinkable TEFLON. The Examiner asserts that "It would have been obvious to one of ordinary skill to include a polyimide material with the lubricious liner of Mische, as Milo teaches that this increases the pushability and column strength of the device". However, Milo does not overcome the deficiencies of Mische et al. discussed above.

It is submitted that neither Mische et al. nor Milo, taken either singly or in combination, would have rendered the subject matter of claim 25 obvious to one of skill in the art at the time the invention was made, and that this rejection of claim 25 can therefore be properly withdrawn.

Claim 27 stands rejected under 35 USC §103(a) as being unpatentable over Mische et al. in view of US Patent 5,938,670 to Keith et al. Specifically, the Examiner asserts that "In light of Keith's teachings, it would have been obvious to one of ordinary skill in the art to optimize the dimensions of the Mische liner to provide more resistance to fluid flow".

Claim 27 depends from, and therefore encompasses all the limitations of, claims 19 and 20. The disclosure of Mische et al., and its deficiencies with respect to independent claims 19 and 20, are discussed above. Keith et al. does not overcome these deficiencies.

It is submitted that neither Mische et al. nor Keith et al., taken either singly or in combination, would have rendered the subject matter of claim 27 obvious to one of skill in the art at the time the present invention was made, and that this rejection of claim 27 should therefore be withdrawn.

Concluding Remarks

Every effort has been made to put the pending claims in condition for allowance. Early reconsideration and allowance of the subject application is respectfully requested.

Should the Examiner have any further concerns regarding the subject application, she is respectfully invited to telephone Janet Sleath or Ann Speckman at 206.382.1191

Respectfully submitted,

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Date: January 27, 2011

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